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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,374	11/29/2001	Michael J. Heller	267/242	4021

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	6

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/997,374	Applicant(s) HELLER, MICHAEL J.	
	Examiner Jeffrey Fredman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 11/29/01.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Priority

1. Applicant has claimed priority to U.S. Application 8/250,951, filed May 27, 1994, now U.S. Patent 5,532,129.The examiner has carefully reviewed U.S. Application 08/250,951 and has wordsearched U.S. Patent 5,532,129 to identify whether the application provides enabling support for the claims of the current application. Specifically, no support was found for the limitation of monitoring the amplification of a nucleic acid sequence within this patent.. Therefore, this application, while claiming priority to 08/250,951 will not be given such priority for the current claims since the parent application lacks enabling support for the current claims.

2. Further, the examiner has reviewed the current specification itself, as well as the parent, U.S. Application 09/724,753, and finds that there is no descriptive support for the method of monitoring amplification other than that found in the claim itself. Since a claim can provide it's own written description, the originally filed claim is not new matter, but the current claim is not entitled to and will not be given priority to any of the parent applications because these applications do not provide descriptive support for the method of monitoring amplification.

Double Patenting

3. Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,162,603 in view of Kidwell et al (U.S. Patent 5,332,659).

Claims 1-17 of U.S. Patent No. 6,162,603 teach a method for detection of a target polynucleotide sequence, comprising the steps of:

providing a first polynucleotide sequence having one or more chromophores;

providing a second polynucleotide sequence hybridized to the first polynucleotide sequence, the second polynucleotide sequence having one or more chromophores arranged in a quenching relationship to the acceptor chromophore of the first polynucleotide sequence when the first polynucleotide sequence and second polynucleotide sequence are hybridized;

exposing a target polynucleotide sequence to the hybridized first and second polynucleotide sequences;

denaturing the hybridized first and second polynucleotide sequences;

hybridizing the first polynucleotide sequence to the target polynucleotide sequence;

hybridizing a third polynucleotide sequence having one or more donor chromophores to the target polynucleotide sequence; and

irradiating the mixture to detect hybridization of the first polynucleotide sequence to the target polynucleotide sequence by fluorescence energy transfer from the one or more donor chromophores of the third polynucleotide sequence to the one or more acceptor chromophores of the first polynucleotide sequence (see claim 1).

Claims 1-17 of U.S. Patent No. 6,162,603 further teach wherein the target polynucleotide sequence comprises DNA RNA or synthetic polynucleotide (see claims 2-3).

Claims 1-17 of U.S. Patent No. 6,162,603 further teach wherein the quenching chromophore is selected from the group consisting of 4,4'-Diisothiocyanatodihydro-stilbene-2,2'-disulfonic acid, 4-acetamido-4'-isothiocyanato-stilbene-2,2'-disulfonic acid, 4,4'-Diisothiocyanatostilbene-2,2'-disulfonic acid, Succinimidyl pyrene butyrate, Acridine isothiocyanate, 4-imethylaminophenylazophenyl-4-isothiocyanate (DABITC), Lucifer Yellow vinyl sulfone, Fluorescein isothiocyanate, Reactive Red 4 (Cibacron Brilliant Red 3B-A), Rhodamine X isothiocyanate, Texas Red (Sulforhodamine 101, sulfonyl chloride), Malachite Green isothiocyanate, or IR144. (see claim 4).

Claims 1-17 of U.S. Patent No. 6,162,603 further teach wherein the first polynucleotide sequence is bound to a solid support. (see claim 6).

Claims 1-17 of U.S. Patent No. 6,162,603 further teach wherein the polynucleotide sequence comprises a plurality of donor chromophores. (see claim 14).

Claims 1-17 of U.S. Patent No. 6,162,603 do not teach monitoring PCR amplification reactions.

Kidwell teaches monitoring of denatured and double stranded nucleic acids in PCR reactions in a homogeneous format during each PCR cycle (column 9, lines 1-19).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the method of Claims 1-17 of U.S. Patent No. 6,162,603 to monitor PCR reactions as taught by Kidwell since Kidwell states "A homogenous assay for polynucleic acid could be a valuable technique for the diagnosis of bacterial or viral infections" (column 9, lines 15-18). An ordinary practitioner would have been motivated to utilize the method of Claims 1-17 of U.S. Patent No. 6,162,603

to monitor PCR reactions in order to be able to diagnose in a rapid and efficient manner

bacterial or viral infections.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Heller (U.S. Patent 5,849,489) in view of Kidwell et al (U.S. Patent 5,332,659).

Heller teaches a method for detection of a target polynucleotide sequence

(column 19), comprising the steps of:

providing a first polynucleotide sequence having one or more chromophores

(column 19, lines 8-22);

providing a second polynucleotide sequence hybridized to the first polynucleotide

sequence, the second polynucleotide sequence having one or more chromophores arranged in a quenching relationship to the acceptor chromophore of the first polynucleotide sequence when the first polynucleotide sequence and second polynucleotide sequence are hybridized (column 19, lines 8-22);

exposing a target polynucleotide sequence to the hybridized first and second polynucleotide sequences (column 19, lines 26-30);

denaturing the hybridized first and second polynucleotide sequences (column 21, lines 20-31);

hybridizing the first polynucleotide sequence to the target polynucleotide sequence (column 19, lines 8-30);

hybridizing a third polynucleotide sequence having one or more donor chromophores to the target polynucleotide sequence (column 19, lines 8-30); and

irradiating the mixture to detect hybridization of the first polynucleotide sequence to the target polynucleotide sequence by fluorescence energy transfer from the one or more donor chromophores of the third polynucleotide sequence to the one or more acceptor chromophores of the first polynucleotide sequence (column 19, lines 31-40)

Heller further teaches wherein the target polynucleotide sequence comprises DNA RNA or synthetic polynucleotide (see column 21, lines 13-31).

Heller further teaches wherein the quenching chromophore is selected from the group consisting of 4,4'-Diisothiocyanatodihydro-stilbene-2,2'-disulfonic acid, 4-acetamido-4'-isothiocyanato-stilbene-2,2'-disulfonic acid, 4,4'-Diisothiocyanatostilbene-2,2'-disulfonic acid, Succinimidyl pyrene butyrate, Acridine isothiocyanate, 4-

imethylaminophenylazophenyl-4-isothiocyanate (DABITC), Lucifer Yellow vinyl sulfone, Fluorescein isothiocyanate, Reactive Red 4 (Cibacron Brilliant Red 3B-A), Rhodamine X isothiocyanate, Texas Red (Sulforhodamine 101, sulfonyl chloride), Malachite Green isothiocyanate, or IR144. (see column 10, table 2).

Heller further teaches wherein the first polynucleotide sequence is bound to a solid support. (see claims 3-4).

Heller further teaches wherein the polynucleotide sequence comprises a plurality of donor chromophores. (see column 18).

Heller does not teach monitoring PCR amplification reactions.

Kidwell teaches monitoring of denatured and double stranded nucleic acids in PCR reactions in a homogeneous format during each PCR cycle (column 9, lines 1-19).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the method of Heller to monitor PCR reactions as taught by Kidwell since Kidwell states "A homogenous assay for polynucleic acid could be a valuable technique for the diagnosis of bacterial or viral infections" (column 9, lines 15-18). An ordinary practitioner would have been motivated to utilize the method of Heller to monitor PCR reactions in order to be able to diagnose in a rapid and efficient manner bacterial or viral infections.

7. Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity at the time this invention was made. Accordingly, Heller et al (U.S. Patent 5,849,489) is disqualified as prior art through 35 U.S.C. 102(e), (f) or (g) in any rejection under 35 U.S.C. 103(a) in

this application. However, this applied art additionally qualifies as prior art under another subsection of 35 U.S.C. 102, specifically 35 U.S.C. 102(b), and accordingly is not disqualified as prior art under 35 U.S.C. 103(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1637

July 15, 2002